

EXHIBIT 78

MODEL 500 SERVICE MANUAL

(MODELS 500, 500E, 500J)

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WARNINGS

1. **Monitor the patient's temperature and vital signs regularly. Reduce the air temperature or discontinue therapy when normothermia is reached, or if vital sign instability occurs.**
2. Heat should not be applied directly to open wounds.
3. Due to the possibility of airborne contamination, the Bair Hugger® Warming Cover should not be applied to surfaces with open infected wounds.
4. Do not apply Bair Hugger® Warming Covers to ischemic limbs, (eg. legs during aortic cross-clamping).
5. If the red Over Temperature Alarm lights up, and/or the audible alarm sounds, turn off the Heating Unit and discontinue use. Refer servicing to an authorized service technician.
6. **The Bair Hugger® Warming Covers are intended for SINGLE PATIENT USE ONLY.**
7. **Explosion Hazard: Do not use in the presence of flammable anesthetics.**

GENERAL MAINTENANCE

The Bair Hugger® Patient Warming System requires no maintenance except for wiping the cabinet and hose clean with a damp cloth and regularly changing the air filter mounted inside the top cover of the unit.

Cleaning the cabinet

To clean the Bair Hugger® cabinet, use a soft cloth lightly dampened with water.

1. Unplug the unit.
2. Do not use a wet saturated cloth to clean the unit. Moisture may seep into the electrical contacts damaging the components.
3. Do not use alcohol or other solvents to clean the cabinet. Solvents may damage the labels and other plastic parts.

ELECTRICAL MAINTENANCE

Electrical Shock Hazard:

Do not disassemble this unit. Refer servicing to an Augustine Medical, Inc. authorized Service Center or contact:

Service Department
Augustine Medical, Inc.
10393 West 70th Street
Eden Prairie, MN 55344
(612)941-8866
(800)733-7775

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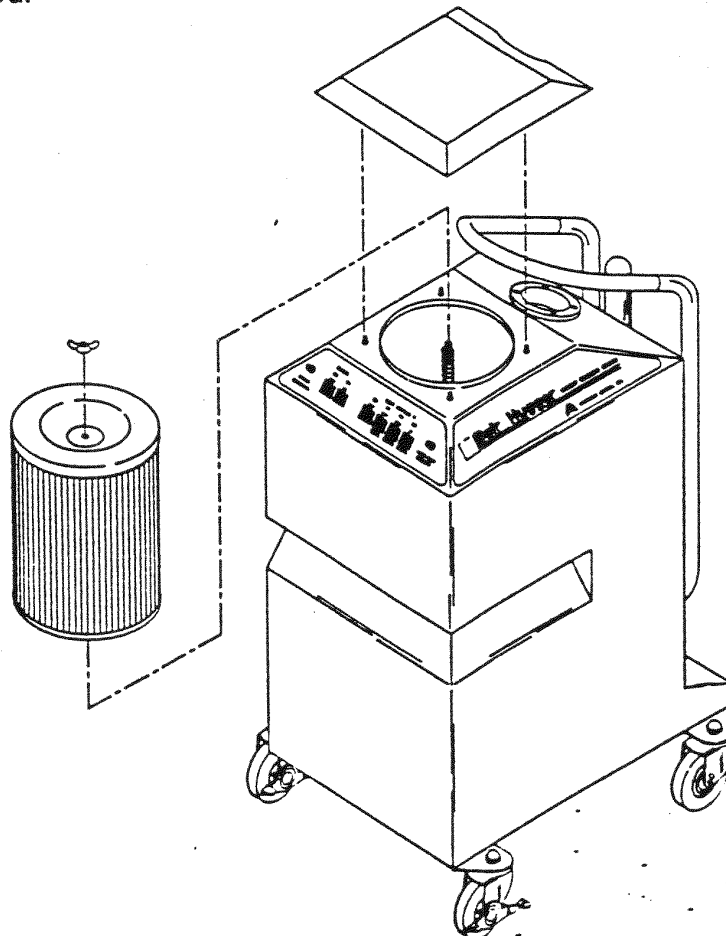
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INSTRUCTIONS FOR CHANGING THE FILTER

Under normal use, the air filter inside the top cover of the heating unit should be changed every 500 hours. You should find the hours of the last filter change located in the back of this book.

1. Make sure to disconnect power to the unit before removing the filter.
2. Remove the service cover by lifting up and removing the wing nut from the top of the filter (Figure 2).
3. Remove the old filter, record the hours indicated on the hour meter on the maintenance sheet in the back of this book.
4. Install the new filter, insure that the filter is seated firmly to fully engage the interlock switch. Unit will not run unless interlock switch is properly engaged.
5. Replace wing nut and service cover.
6. Plug in unit and turn on to insure that the filter interlock is properly seated.



(FIGURE 2)

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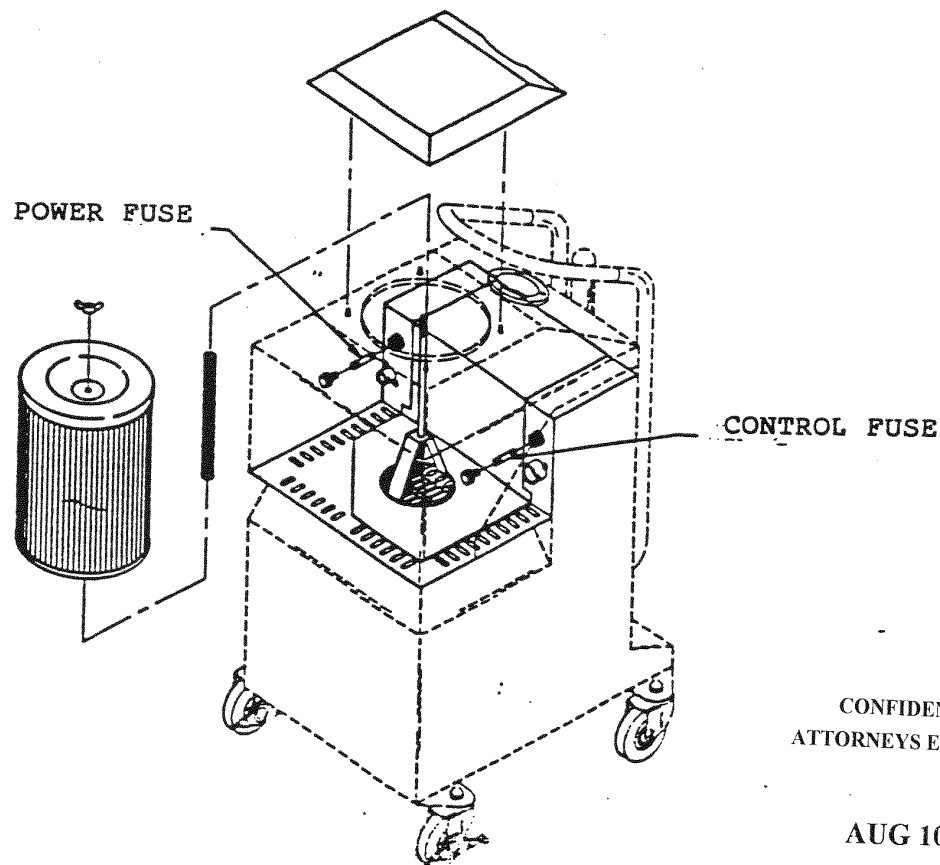
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INSTRUCTIONS FOR REPLACING FUSES

There are two fuses located inside the filter housing. They are labeled 15A and .062A. There is a replacement .062A fuse in the filter compartment of each new Heating Unit.

1. Make sure to disconnect power to the unit before replacing the fuses.
2. To replace the fuses, remove the service cover by lifting up and remove wing nut from the top of the filter.
3. Remove the filter.
4. Unscrew the fuse holder cap, remove the old fuse, and insert new fuse.
5. Replace the fuse holder cap, filter, wing nut and service cover.
6. Insure that the filter is seated firmly to fully engage the interlock switch. Unit will not run unless interlock switch is properly seated.
7. Record the maintenance action taken and hours on the maintenance sheet in the back of this book.
8. Plug in Unit and turn on to insure that the filter interlock is properly seated.



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MODEL 500 BAIR HUGGER® TEMPERATURE TEST **INSTRUCTIONS**

TO TEST NORMAL OPERATING TEMPERATURES:

Attach hose to temperature test kit, turn power on, select temperature setting you wish to test. After approximately 5 minutes running time, check the temperature on the test kit. This should read approximately 10° F higher than the heat setting on front of the Bair Hugger. Note: the Heating Unit has a $\pm 5^\circ$, cycle this may show on the test kit.

TO TEST FOR OVER TEMPERATURE ALARMS:

CAUTION: MAKE SURE BAIR HUGGER IS UNPLUGGED WHEN SETTING UP THIS TEST, OR ELECTRIC SHOCK COULD OCCUR.

Tools required for this procedure include:
Temperature Test Kit, Medium Phillips
Screw Driver and Needle Nose Pliers.

1. Remove service lid.
2. Remove filter.
3. Remove hose.
4. Remove 14 screws securing power head assembly.
5. Unplug power head plug connectors. This is done by depressing the two finger grips on the plug assembly.
6. Remove power head assembly.
7. Remove the 19 screws that secure the filter seat.

****Note****

That the 6 screws securing exhaust gasket should not be removed.

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8. Carefully remove filter seat by lifting up on filter seat near the hour meter. Lift filter seat just enough to clear exhaust tube.

****Note****

The interlock switch wires are still connected to filter seat, making it impossible to remove filter seat completely.....

Pull filter seat out enough to clear exhaust tube.....

When filter seat clears exhaust tube, lay filter seat on hour meter shelf leaving the interlock switch wires connected.

9. Observe and locate the Blue 18 AWG wire that connects to P-3 on the controller, carefully disconnect this wire from P-3.
10. Replace filter seat.

****Note****

There is no need to secure the filter seat as P-3 will need to be reconnected after test completion.....

At this time pull up on the interlock switch plug until it clicks into extended position.....

This will bypass the interlock safety mechanism allowing unit to operate.

11. Replace power head and reconnect power head plug connectors, note you should hear an audible click when pin connectors are properly seated.
12. Reconnect hose and connect to temperature test kit.
13. Power up the unit and wait for the audible or visual alarm to activate. When alarm activates note temperature on test kit. This should meet manufacture specifications.
14. When over temperature alarm is verified, unplug unit, reconnect P-3 on the controller.

**** Note****

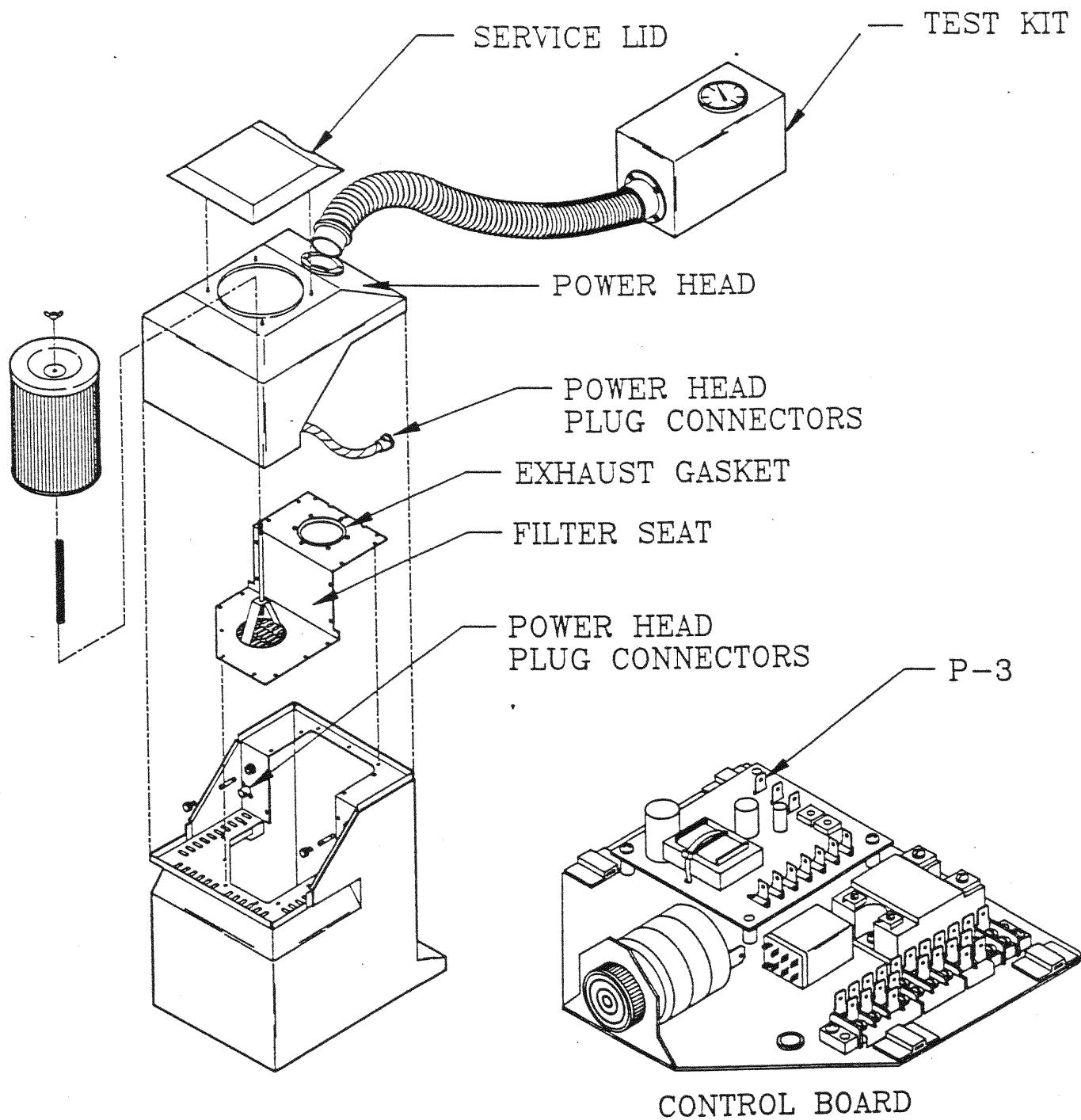
Be sure this connection is secure as the operating temperature circuit is by passed when this connection is not made.

15. Reverse steps 1-8 insure that all connections are made. Reconnect power head plug connectors, listen for audible click indicating that the connections are secure.

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TROUBLESHOOTING AND SERVICE DATA

<u>PROBLEM</u>	<u>POSSIBLE CAUSE</u>	<u>REMEDY</u>
Unit does not turn on.	1. Check power cord plug. 2. Check power fuse. 3. Power head plug connection. 4. Filter should be firmly seated.	Make sure there is voltage at the receptacle. Replace fuse if blown. Disconnect and reconnect snapping firmly in place.
Unit is on but does not circulate air. (Power & Overtemp. lights are on).	1. Power head plug connection. 2. Return unit to nearest authorized dealer.	Disconnect and reconnect snapping firmly in place.
Unit circulates air but does not heat.	1. Check control fuse. 2. Check condition of thermocouple lead wires. 3. Check connections of the thermocouple leads on the control unit. (TC- & TC+) 4. Check voltage at DC output of control unit. (12 VDC approx.) 5. Check solid state relay AC output. 6. Check thermostat for continuity. 7. Power head plug connection.	Replace blown fuse. Replace thermocouple assembly if defective. Reattach any loose connections. Recrimp loose flag terminals. If no voltage, contact service rep. If no AC output, replace relay. If thermostat is open let unit cool and restart. Disconnect and reconnect snapping firmly in place.
Unit heats on some temperature settings but not on others (i.e. unit heats on low and high but not on medium).	1. Check connections of wire corresponding to the setting that is not producing heat (i.e. if unit is not producing heat on the medium setting, check connections of the green wire at the switch and control unit). 2. Power head plug connection.	Reconnect wires as required. Disconnect and reconnect snapping firmly in place.

PARTS LIST FOR: MODEL 500 BAIR HUGGER		
DRAWING #	DESCRIPTION	PART#
NOT SHOWN	EXPLOSION RISK LABEL	100310
NOT SHOWN	GROUND LABEL	100320
NOT SHOWN	FUSE LABEL	100330
NOT SHOWN	CAUTION LABEL	100340
(5.)	FUSE HOLDER	100901
(6.)	CONTROL FUSE	100910
(7.)	POWER FUSE	100920
(8.)	SPARE FUSE HOLDER	100930
(9.)	.5" GROMMET	101010
(10.)	CORD STRAIN RELIEF	101100
(11.)	TERMINAL BAR	101401
	TERMINAL JUMPER (4)	101410A
	TERMINAL JUMPER (3)	101410B
	TERMINAL JUMPER (2)	101410C
(12.)	RED INDICATOR LIGHT	101901Q
(13.)	GREEN INDICATOR LIGHT	101910Q
(14.)	B-200 THERMOSTAT	102125
(15.)	HOUR METER	102130
6.)	REGISTRATION CARD	102303
NOT SHOWN	POWER CORD	103101
(18.)	CONTROL UNIT	103110
(19.)	SOLID STATE RELAY	103120A
(20.)	ALARM RELAY	103130
(21.)	CONTROL THERMOCOUPLE	103140A
(22.)	AUDIBLE ALARM	103150
NOT SHOWN	RESISTER HARNESS (SEE DETAIL "C")	103160
(24.)	CABINET (PAINTED)	500101
	CABINET COVER	500102
(25.)	SERVICE LID	500103
(27.)	BASE PLATE	500105
(28.)	FILTER SEAT	500107
(29.)	FILTER .2 MICRON	500109
(30.)	CASTER	500110
(31.)	CASTER LOCKING	500111
(32.)	BLOWER HOUSING	500113
(33.)	BLOWER MOUNTING BRACKET	500115
(34.)	HEATER CARTRIDGE	500117
(35.)	EXHAUST TUBE	500119
(36.)	HOSEWRAP CURVE	500120
	HOSEWRAP STRAIGHT	500121
	STANDOFF #2	500125

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DRAWING #	DESCRIPTION	PART #
	WASHER #1	500127
	WASHER #2	500129
(37.)	HANDLE	500130
(38.)	HOSE COUPLING FLANGE	500131
(39.)	BLWR MTG BRKT SPACER/GROMMET	500133
(40.)	FRONT CONTROL LABEL	500135
(41.)	LOGO LABEL SET	500137
(42.)	850W HEATER	500139
(43.)	MOTOR	500140
(44.)	BLOWER WHEEL ALUM HIGH SPEED	500141
(45.)	GASKET SET (3) FILTER SEAT	500143
(46.)	SWITCH 7 POSITION DRY CONTACT	500145
(47.)	INTERLOCK SWITCH	500146
(48.)	WIRE HARNESS	500149
(49.)	(9PIN) POWER HEAD PLUG CONNECTION	500149A
(50.)	(4PIN) POWER HEAD PLUG CONNECTION	500149B
(51.)	(4PIN) POWER HEAD PLUG CONNECTION	500149C
(52.)	(9PIN) POWER HEAD PLUG CONNECTION	500149D
NOT SHOWN	CABLE WRAP	500149E
(57.)	45 DEGREE DUAL TAB	500149L
(59.)	HOSE ASSEMBLY FOUR FOOT	500150
NOT SHOWN	OPERATIONS MANUAL	500151
NOT SHOWN	SERVICE MANUAL	500153
NOT SHOWN	MASTER CARTON	500155A
NOT SHOWN	INNER CARTON	500155B
NOT SHOWN	TOP FOAM PACKING	500155C
NOT SHOWN	SMALL CORNER PACKING	500155D
NOT SHOWN	LARGE FOAM PACKING	500155E
NOT SHOWN	BOTTOM FOAM PACKING	500155F
NOT SHOWN	SERIAL NUMBER LABEL	500159
NOT SHOWN	UL LABEL	500160
NOT SHOWN	INSTRUCTION LABEL	500161
(68.)	HOSE WRAP BALL PLUGS	500163
NOT SHOWN	GROMMET ONE INCH	500164
(70.)	HEATER CARTRIDGE GROMMET	500165
NOT SHOWN	BASE PLATE GASKET	500167
(72.)	BLOWER INLET RING	500168
NOT SHOWN	SWITCH RETAINING CLIP	500169
(74.)	EXHAUST TUBE GASKET	500170
NOT SHOWN	EXHAUST SEAT GASKET	500170A
(76.)	8/32X3/8 STANLS MACH. SCREW	500147A
NOT SHOWN	6/32X3/8 STANLS FLTHD MCSCREW	500147B
NOT SHOWN	8/32X1/2 PHL MACH SCRW	500147C
NOT SHOWN	8/32 NYLON LOCKNUT	500147D

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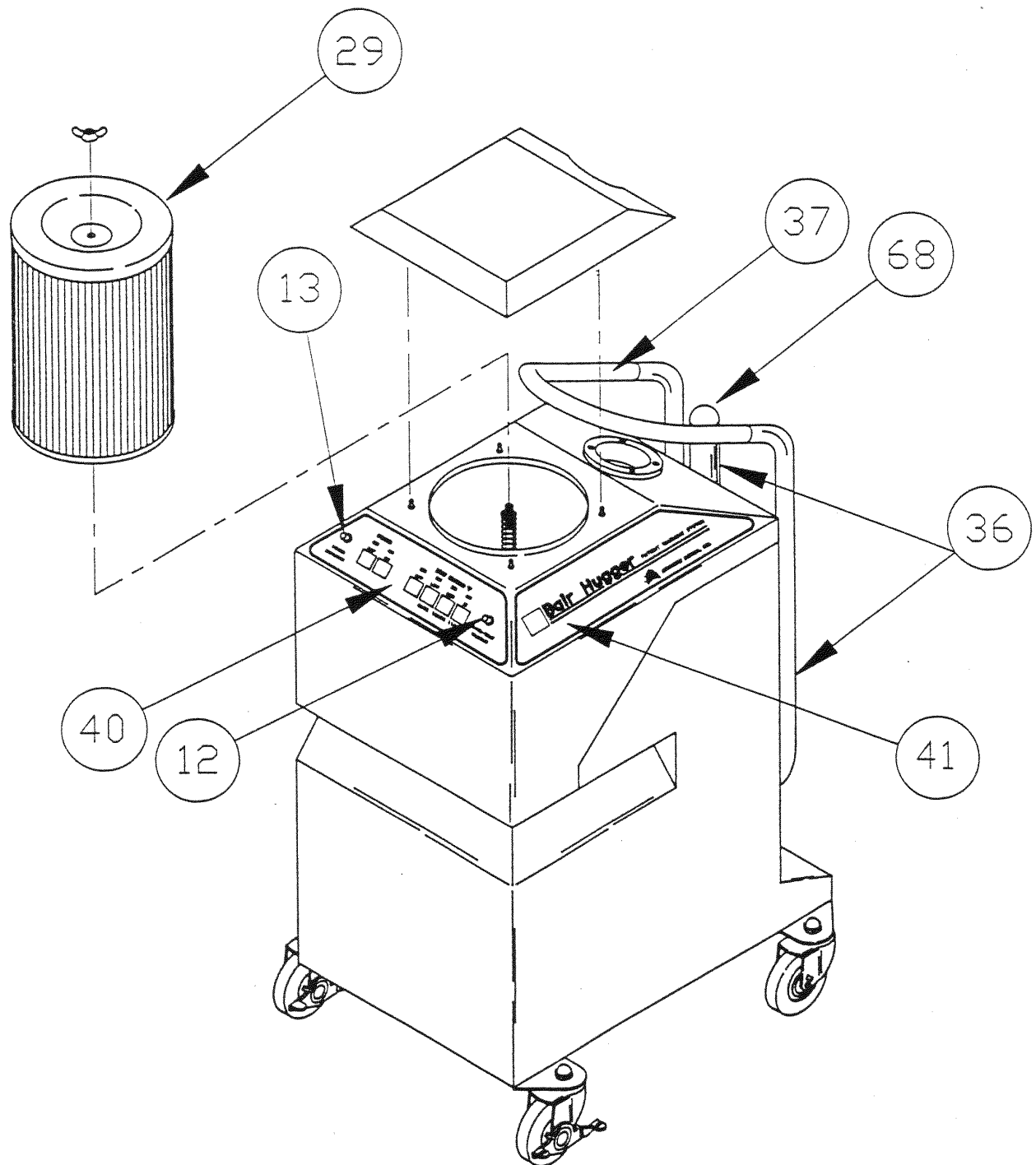
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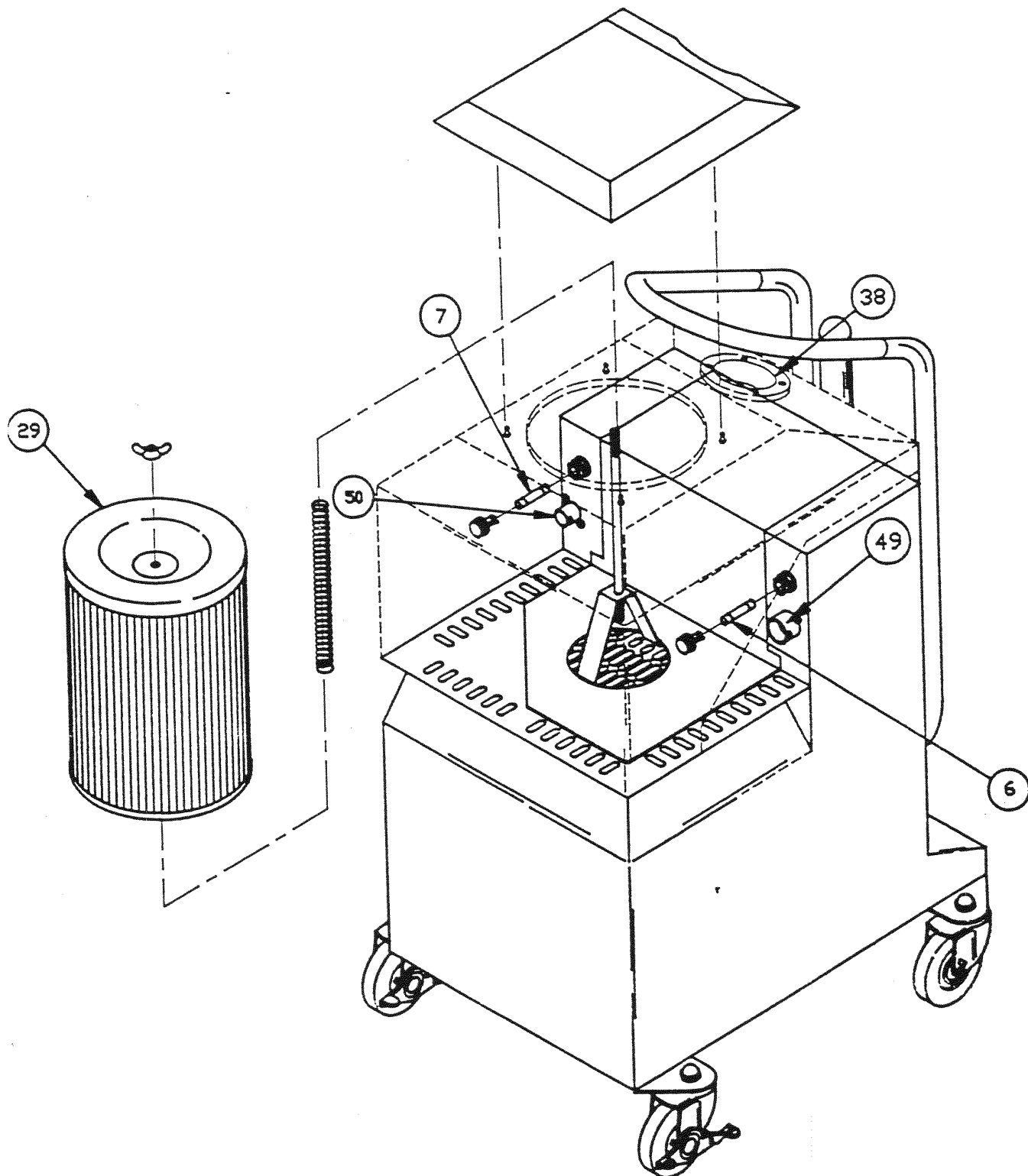


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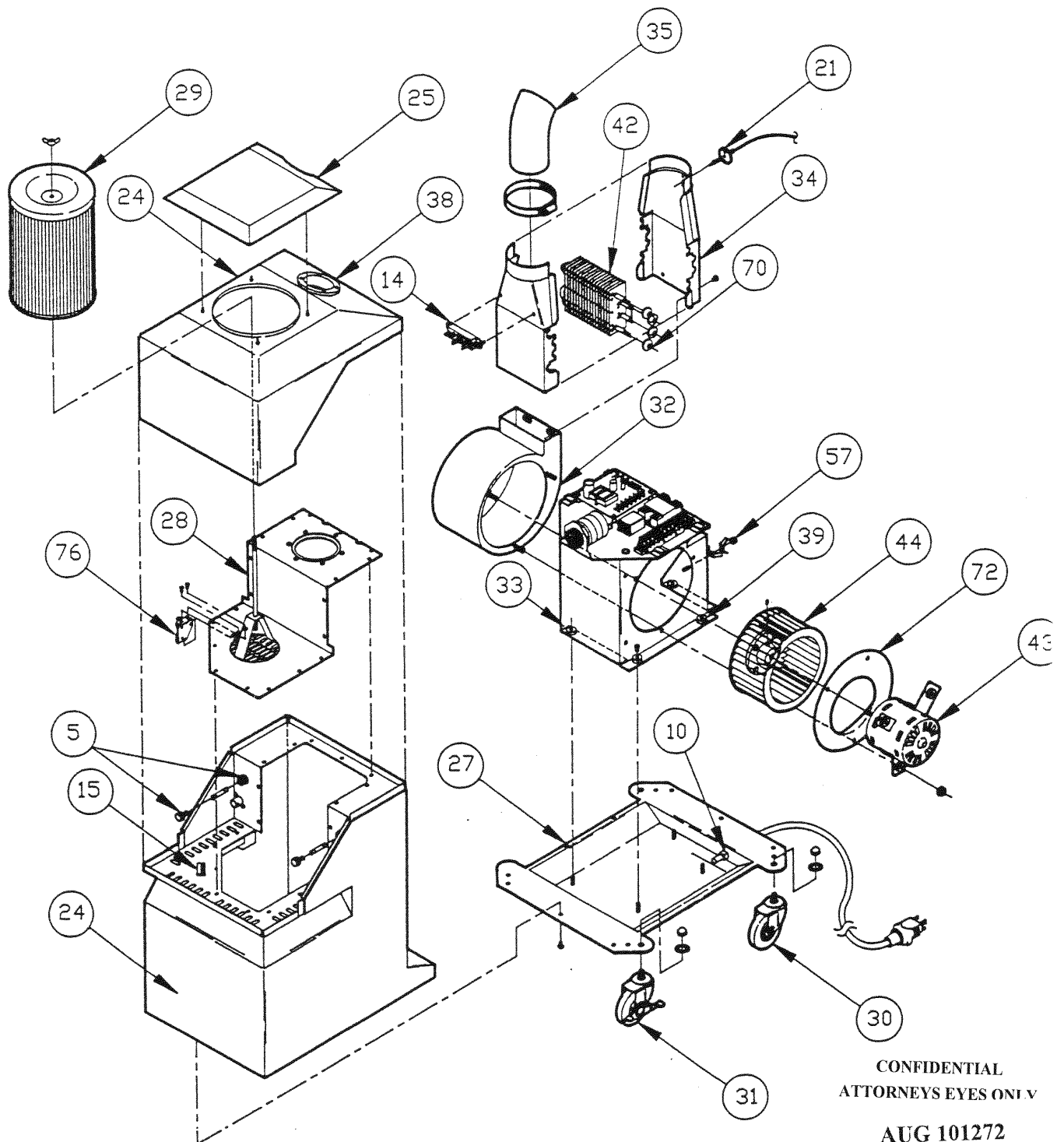


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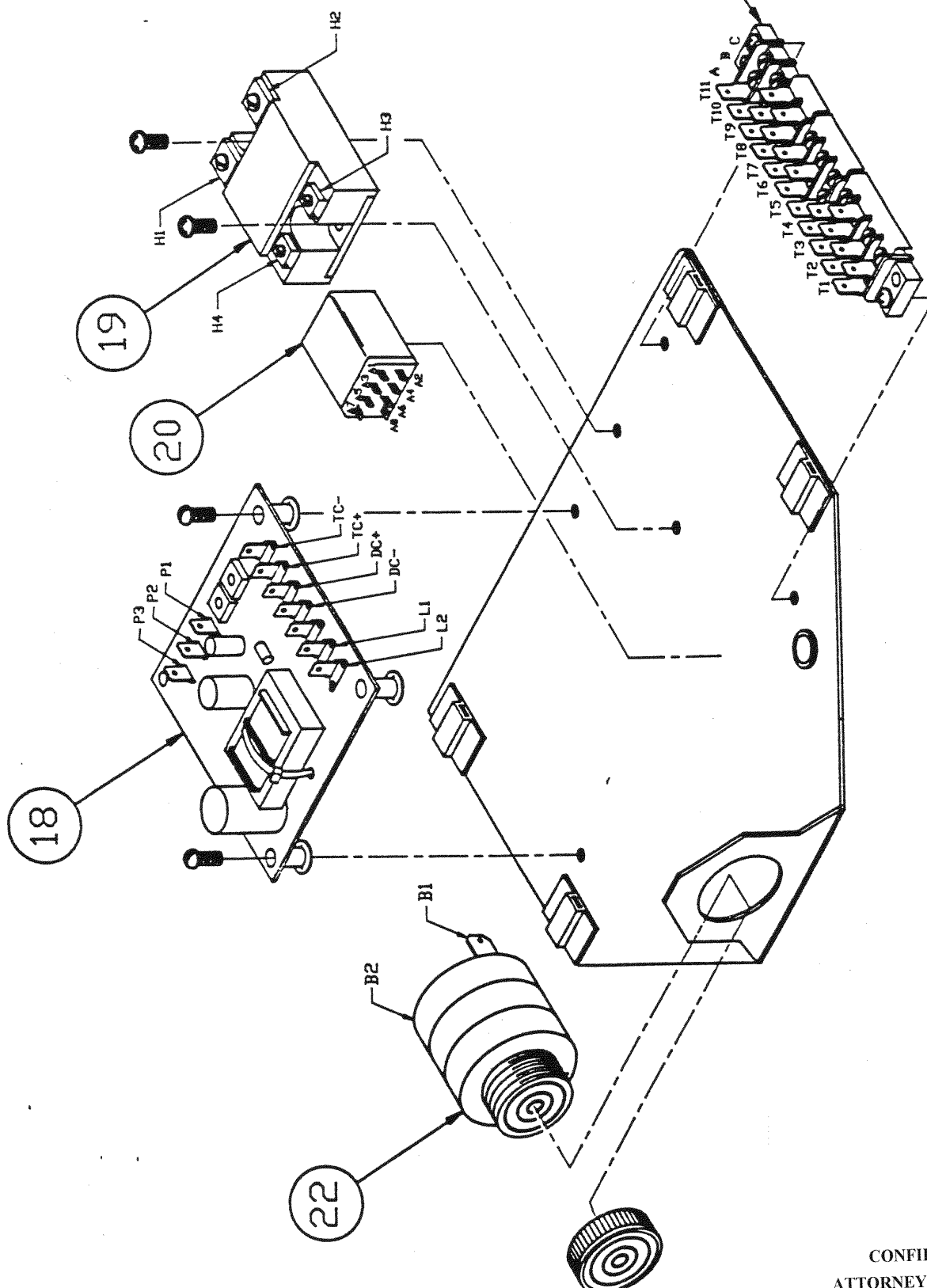
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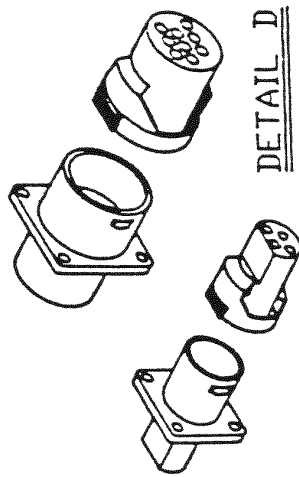


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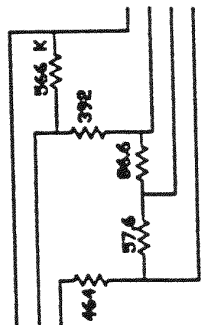
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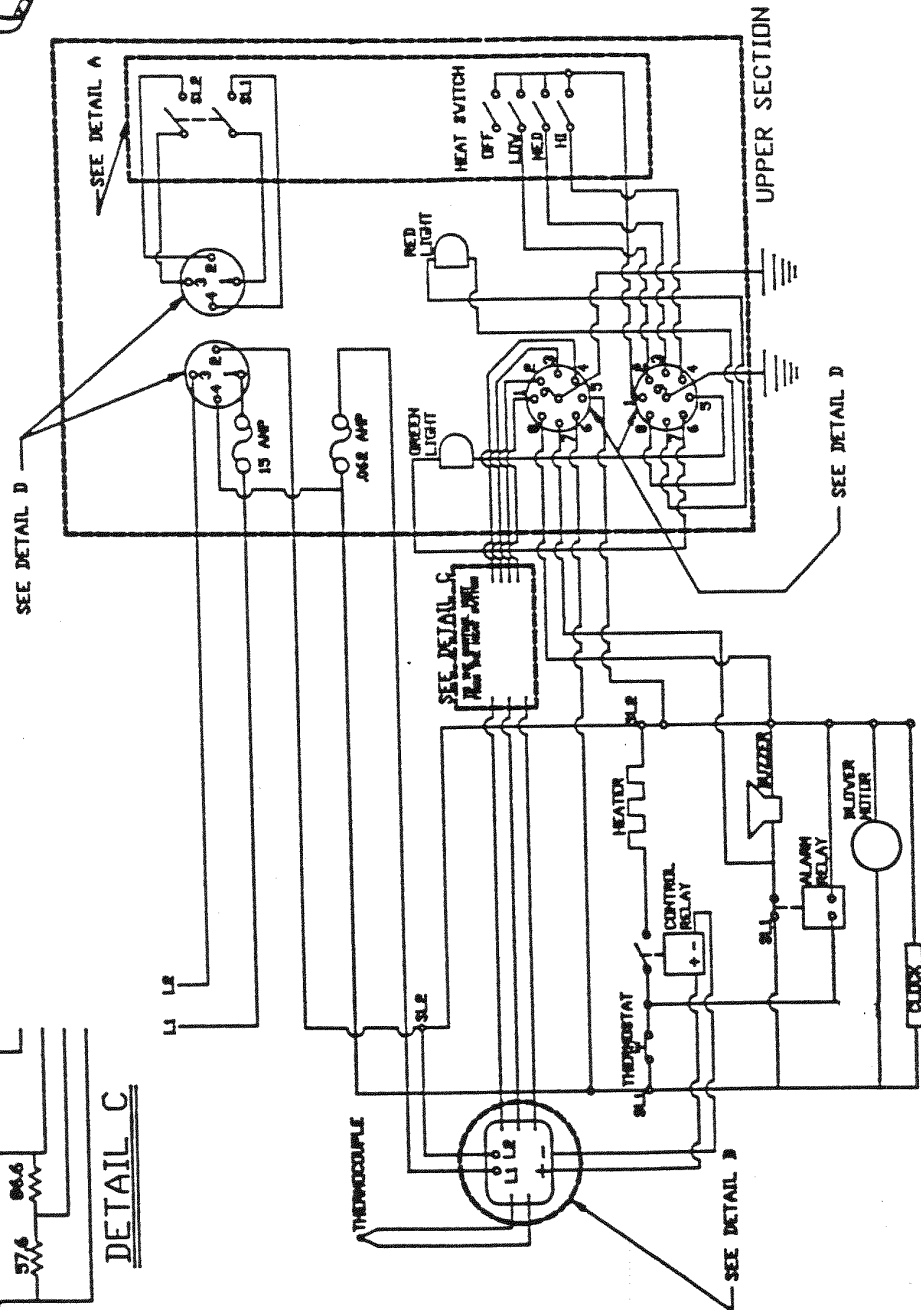
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DETAIL D



DETAIL C



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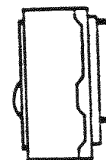
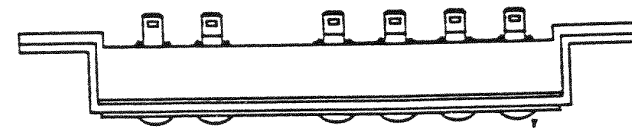
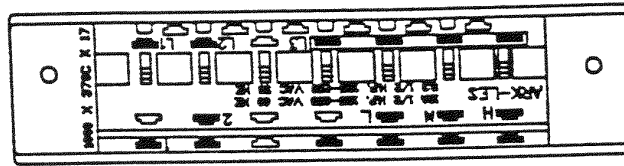
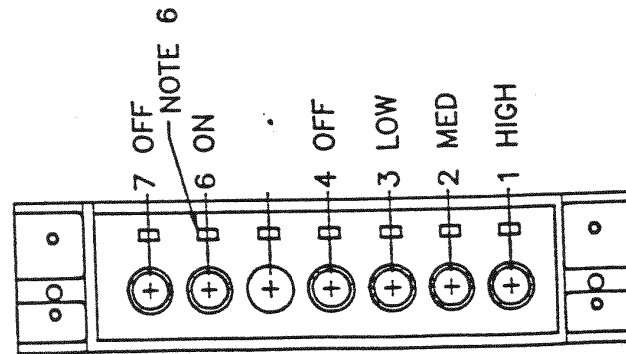
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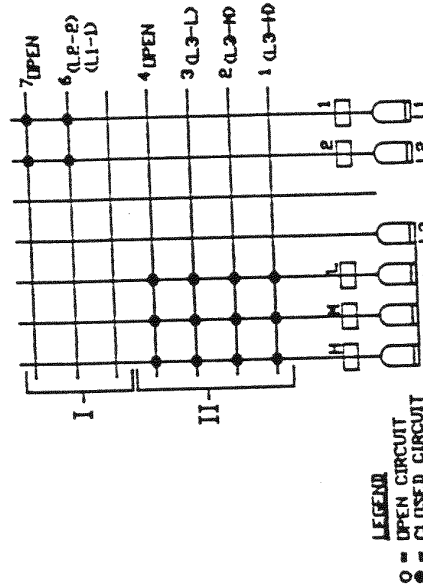
ARK-LES CORPORATION

ASSEMBLY, SWITCH 7-BUTTON, PART #1000 370C X 17



NOTES:

1. A.Q.C. MALE TERMINALS .250 X .032
2. RATING: 10A 1/2 HP 125 - 250 VAC
8.3A 1/2 HP 125 - 250 VAC
3. BUTTON ACTIVATION FORCE: TWO TO FIVE POUNDS
4. SWITCH MUST NOT HANG UP WHEN 2 OR MORE BUTTONS ARE PRESSED SIMULTANEOUSLY AND THEN RELEASED.
5. CIRCUITRY MUST BREAK BEFORE MAKE
6. INDICATOR VISIBLE THRU MEMBRANE WINDOW AFTER BUTTON IS DEPRESSED
7. SECTION I INDEPENDENT OF SECTION II



DETAIL A

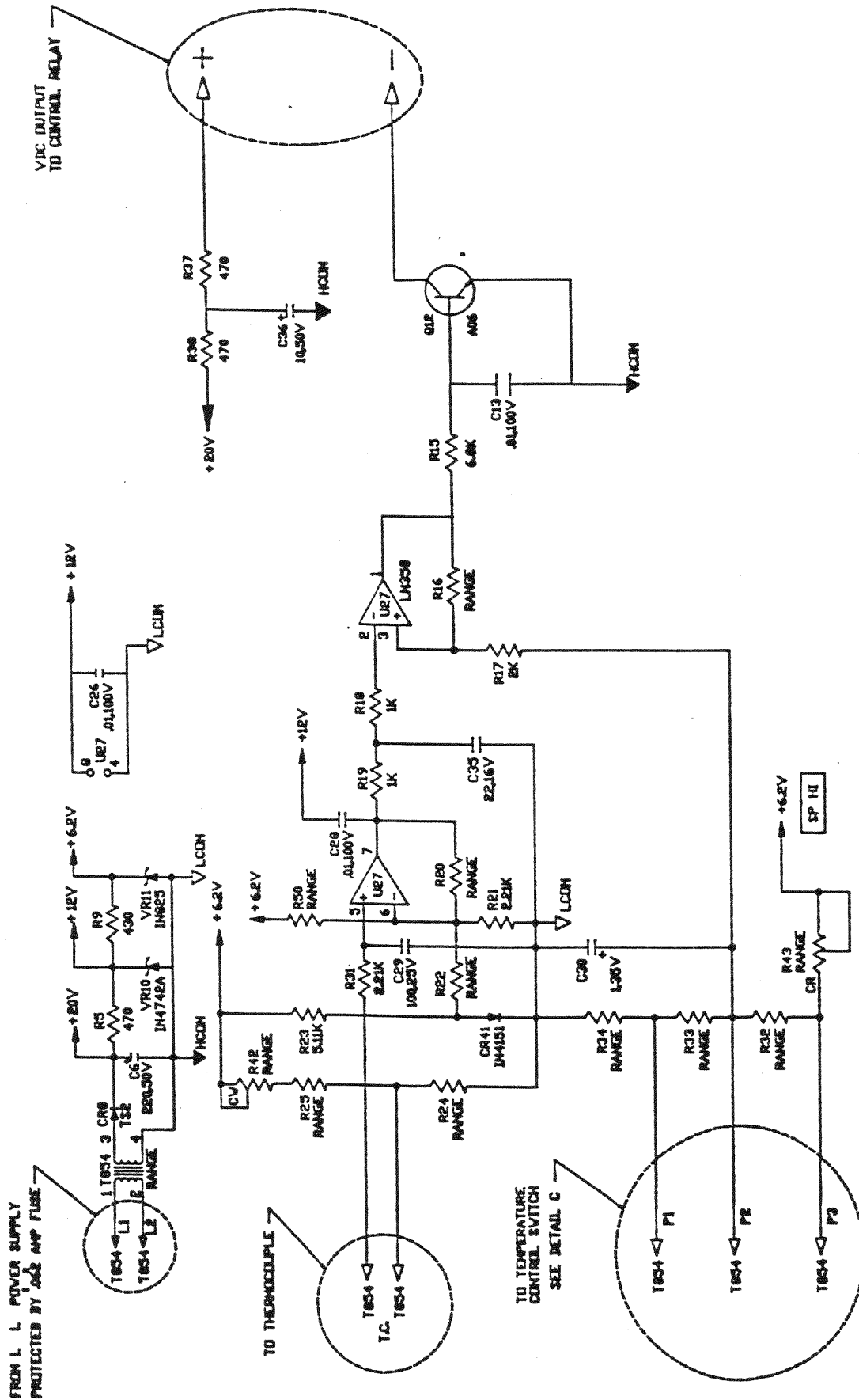
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PART NO. ADD7-1308



DETAIL B

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SPECIFICATIONS

Model 500 Bair Hugger® Patient Warming System

CHARACTERISTICS

Dimensions:

25.5" High x 14" Deep x 15" Wide

Weight:

45 Pounds

Cabinet Construction:

18 Ga steel with painted enamel finish.

CONTROL SYSTEM

Temperature Setting:

The temperature settings on the control switch indicate the average temperature of the air surrounding the patient using a Bair Hugger Warming Cover. Actual air temperature at the hose outlet is approximately 10° higher than the average temperature.

**Average Temperature of Air
Surrounding Patient**

<u>Setting</u>	<u>Temperature</u>
Heat Off.....	Ambient Temp
Low.....	90° ± 5°F (33.0°C)
Medium.....	100° ± 5°F (37.6°C)
High.....	110° ± 5°F (43.1°C)

Filter System:

.02 Micron Filter

HEATING SYSTEM

Motor:

1/30 HP, Single Phase, 3600 rpm Motor

Heater:

850W Sealed tube heating element

ELECTRICAL SYSTEM

Characteristics (Std):

115V, 60Hz., 9.5 Amps

Power Cord:

Grey, 15 foot long, 14 GA cord with hospital grade plug.

Current Leakage:

Meets hospital standards for leakage current.

Fuses:

15 Amp and .062 Amp Slo Blo

Thermostat: B-200

SAFETY SYSTEM

Filter Seat Interlock Switch

Thermocouple:

Heater will shut off if the thermocouple is physically damaged.

High Temperature Thermostat:

Thermal cutoff shuts off the heater at a preset high temperature of 130°F to 140°F at the end of the hose.

High Temperature Alarm:

Visual-red neon light on front panel and an audible alarm.

COVER SPECIFICATIONS

Dimensions:

Upper Body: 80" x 21"

Lower Body: 34" x 36"

Weight:

5 oz.

Material:

Polyethylene and tissue paper laminate.

SPECIFICATIONS

Model 500-E Bair Hugger® Patient Warming System

CHARACTERISTICS

Dimensions:

647.7 mm High x 355.6mm Deep x 381 mm Wide

Weight:

20.41 Kg

Cabinet Construction:

18 Ga steel with painted enamel finish.

CONTROL SYSTEM

Temperature Setting:

The temperature settings on the control switch indicate the average temperature of the air surrounding the patient using a Bair Hugger Warming Cover. Actual air temperature at the hose outlet is approximately 10° higher than the average temperature.

Average Temperature of Air Surrounding Patient

<u>Setting</u>	<u>Temperature</u>
Heat Off.....	Ambient Temp
Low.....	90° ± 5°F (33.0°C)
Medium.....	100° ± 5°F (37.6°C)
High.....	110° ± 5°F (43.1°C)

Filter System:

.02 Micron Filter

HEATING SYSTEM

Motor:

1/30 HP, Single Phase, 3000 rpm Motor

Heater:

850W Sealed tube heating element

ELECTRICAL SYSTEM

Characteristics (Std):

220V, 50Hz., 4.5 Amps

Power Cord:

Grey, 15 foot long, 14 GA cord with hospital grade plug.

Current Leakage:

Meets hospital standards for leakage current.

Fuses:

15 Amp and .062 Amp Slo Blo

Thermostat: B-200

SAFETY SYSTEM

Filter Seat Interlock Switch

Thermocouple:

Heater will shut off if the thermocouple is physically damaged.

High Temperature Thermostat:

Thermal cutoff shuts off the heater at a preset high temperature of 54.44°C to 61.11°C at the end of the hose.

High Temperature Alarm:

Visual-red neon light on front panel and an audible alarm.

COVER SPECIFICATIONS

Dimensions:

Upper Body: 2.03 cm x 533.4 mm

Lower Body: 863 mm x 914 mm

Weight:

141.75 Grams

Material:

Polyethylene and tissue paper laminate.

SPECIFICATIONS

Model 500-J Bair Hugger® Patient Warming System

CHARACTERISTICS

Dimensions:

647.7 mm High x 355.6mm Deep x 381 mm Wide

Weight:

20.41 Kg

Cabinet Construction:

18 Ga steel with painted enamel finish.

CONTROL SYSTEM

Temperature Setting:

The temperature settings on the control switch indicate the average temperature of the air surrounding the patient using a Bair Hugger Warming Cover. Actual air temperature at the hose outlet is approximately 10° higher than the average temperature.

**Average Temperature of Air
Surrounding Patient**

<u>Setting</u>	<u>Temperature</u>
Heat Off.....	Ambient Temp
Low.....	90° ± 5°F (33.0°C)
Medium.....	100° ± 5°F (37.6°C)
High.....	110° ± 5°F (43.1°C)

Filter System:

.02 Micron Filter

HEATING SYSTEM

Motor:

1/30 HP, Single Phase, 3000 rpm Motor

Heater:

850W Sealed tube heating element

ELECTRICAL SYSTEM

Characteristics (Std):

100V, 50Hz., 10.1 Amps

Power Cord:

Grey, 15 foot long, 14 GA cord with hospital grade plug.

Current Leakage:

Meets hospital standards for leakage current.

Fuses:

15 Amp and .062 Amp Slo Blo

Thermostat:

B-200

SAFETY SYSTEM

Filter Seat Interlock Switch

Thermocouple:

Heater will shut off if the thermocouple is physically damaged.

High Temperature Thermostat:

Thermal cutoff shuts off the heater at a preset high temperature of 54.44°C to 61.11°C at the end of the hose.

High Temperature Alarm:

Visual-red neon light on front panel and an audible alarm.

COVER SPECIFICATIONS

Dimensions:

Upper Body: 2.03 cm x 533.4 mm

Lower Body: 863 mm x 914 mm

Weight:

141.75 Grams

Material:

Polyethylene and tissue paper laminate.

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MODEL 500 MAINTENANCE RECORD

SERIAL NUMBER: _____

DATE	HOUR METER READING	MAINTENANCE ACTION PERFORMED	INITIALS
		INSTALL FILTER AND PERFORM TEMPERATURE AND LEAKAGE TESTS	